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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,317	07/15/2003	Yunping Li	BBRI-2008US01	7947
7590	01/19/2006		EXAMINER	
Kevin M. Farrell Pierce Atwood Suite 350 One New Hampshire Avenue Portsmouth, NH 03801			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/620,317	<b>Applicant(s)</b> LI ET AL.	
	<b>Examiner</b> Phyllis G. Spivack	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicants' Amendment filed October 26, 2005 is acknowledged. Claims 12-35 are canceled. Claims 1-11 remain under consideration.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because the abstract is no longer limited to the subject matter that is presently claimed. Correction is required. See MPEP § 608.01(b).

The rejections of claims 12-35 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification; of claim 30 under 35 U.S.C. 102(b) as being anticipated by Artech et al., Journal of Pharmacology and Experimental Therapeutics; and of claim 29 under 35 U.S.C. 103 as being unpatentable over Adamson et al., American Journal of Obstetrics and Gynecology, in view of Balboa et al., Journal of Biological Chemistry, are moot following the cancellation of the claims.

In the last Office Action claims 1-12 and 16-19 were rejected under 35 U.S.C. 102(a) as being anticipated by Li et al., Anesthesiology.

Applicants argue a declaration under 37 CFR 1.132 has been filed establishing that the reference is describing Applicants' own work and the persons listed other than Applicants were merely working under the direction of the Applicants.

No official filing of a declaration is noted. An Examiner is no longer able to have papers entered into the record. Applicants' unofficial declaration that was FAXed to the Examiner on September 22, 2005 is not signed by Kathleen Morgan. Further, there is no mention of a fourth author, H. Je.

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The rejection of record under 35 U.S.C. 102(a) as being anticipated by Li et al., Anesthesiology, is maintained for the reasons of record.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the prevention or delaying of preterm uterine contractions in a pregnant mammal comprising administering a compound that inhibits kinase activity such that a decrease in the levels of both phosphorylated ERK and phosphorylated caldesmon in the pregnant mammal is achieved. The specification provides support for delaying preterm uterine contractions comprising administering the single compound designated U0126.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prevention or delaying of preterm uterine contractions in a pregnant mammal.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the area of obstetrics.

The broad recitation "a compound which inhibits kinase activity" is inclusive of a broad range of compounds that exhibit diverse clinical activity. For example, members of the MAP kinase family, as ERK's, operate in various organ systems, as disclosed by Manolagas et al., U.S. Patent 6,416,737. A successful treatment modality for one MAPKK inhibitor, such as U0126, does not presage success following the administration of another such inhibitor in delaying preterm uterine contractions in a pregnant mammal.

The breadth of the claims

The claims are broad and inclusive of any inhibitor of kinase activity.

The amount of direction or guidance provided and the presence or absence of working examples

All working examples are limited to the administration of U0126.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to other compounds that are kinase inhibitors that would be preferred for preventing or delaying preterm uterine contractions in a pregnant mammal. The skilled artisan would expect the interaction of a particular kinase inhibitor in the prevention or delaying of preterm uterine contractions to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding. No direction is provided to distinguish therapy among the various kinase inhibitors. Absent reasonable *a priori* expectations of success for using a particular kinase inhibitor other than U0126 to delay preterm uterine contractions in a pregnant mammal, one skilled in the obstetrics arts would have to test extensively many compounds to discover which particular kinase inhibitor shows efficacy in preventing or delaying preterm uterine contractions in a pregnant mammal such that a decrease in the levels of both phosphorylated ERK and phosphorylated caldesmon in the pregnant mammal are achieved. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 15, 2006

  
Phyllis Spivack

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**PHYLLIS SPIVACK  
PRIMARY EXAMINER**